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Atty. Dkt. No. 084335-0134 Appl. Ser. No. 09/806,462

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Koji KIGAWA et al.

Title:

METHOD FOR PREPARING HIGH

PERFORMANCE RECA-LIKE RECOMBINASE/SINGLE-STRANDED NUCLEIC ACID

PROBE COMPLEX AND UTILIZATION THEREOF

Appl. No.:

09/806,462

Filing Date: 03/22/2002

Examiner:

Strzelecka, Teresa E.

Art Unit:

1645

Mail Stop PATENT APPLICATION Commissioner for Patents PO Box 1450 Alexandria, Virginia 22313-1450

CERTIFICATE OF EXPRESS MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service's "Express Mail Post Office To Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450. EL979071306 US February 24, 2004 (Express Mail Label Number) (Date of Deposit) Suzanne Langley (Printed Nam (Signature)

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie art reference against the claims of the present application.

#### TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

#### RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08, or its foreign counterpart, was cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner. An English-language counterpart of the foreign-language documents has been provided where readily available. The absence of a translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§ 609).

The European Search Report cites EP 0 687 738 and WO 98/08975. Applicants have listed WO 98/08975 on the enclosed form PTO/SB/08 and provided a copy herewith. EP 0 687 738, (published December 20, 1995), corresponds to WO 95/18236, (published July 6, 1995). Applicants have listed WO 95/18236 on the enclosed from PTO/SB/08 and provided a copy herewith. WO 95/18236 is a Japanese language document, which, as indicated in the abstract, relates to:

A method for detecting the presence of a double-stranded target nucleic acid sequence in an immobilized cell or structure, which method involves the step of immobilizing a cell or a cell structure in such a manner as to permit the invasion by a nucleic acid probe and the step of preparing a probe-RecA composite comprising a single-stranded probe and a RecA protein bonded to each other stably. The presence of a target double-stranded nucleic acid sequence is detected by binding the probe-RecA composite to a target double-stranded nucleic acid sequence through the reaction therebetween under the condition where the target nucleic acid sequence does not undergo denaturation and detecting the RecA protein contained in the composite. The invention method provides a diagnostically important method whereby the position of a specified gene or a regulatory region thereof in a chromosome or the presence of a virus-origin nucleic acid sequence can be determined or visualized readily at a high sensitivity.

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In addition to WO 95/18236, Applicants have also listed U.S. 5,965,361 on the enclosed form PTO/SB/08 and provided a copy herewith. U.S. 5,965,361 issued from the U.S. national stage application of WO 95/18236.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

### **STATEMENT**

The undersigned hereby states in accordance with 37 CFR §1.97(e)(1) that each item of information contained in this supplemental information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to filing of this Statement.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Date Submitted: February 24, 2004

(use as many sheets as necessary)

Sheet of 1

Complete if Known			
Application Number	09/806,462		
Filing Date	03/22/2002		
First Named Inventor	Koji KIGAWA		
Group Art Unit	1645		
Examiner Name	Strzelecka, Teresa E.		
Attorney Docket Number	084335-0134		

			~	U.S. PATENT DOCUMENTS	8	
Examiner Cite Initials* No.1	0	U.S. Patent Document			Date of Publication of	Pages, Columns, Lines, Where Relevant
		Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
	A1	5,965,361		Kigawa et al.	10/12/1999	
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FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Ciffice Milimber	ment nd Code <sup>5</sup> f known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	A2	WO98/08975		Kigawa et al.	03/05/1998		
	A3	WO95/18236		Kigawa et al.	07/06/1995		

NON PATENT LITERATURE DOCUMENTS					
Examiner Cite No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	A4	Supplementary European Search Report, 16 January 2004, Munich Germany (2 pgs.).			

Examiner		Date	
Signature		Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

<sup>1</sup> Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 

Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 

Applicant is to place a check mark here if English language Translation is attached.